UNITED STATES DISTRICT COURT WESTERN DISTRICT OF NORTH CAROLINA CHARLOTTE DIVISION

No. 3:17-CV-37-FDW

(Consolidated with No. 3:17cv46)

UNITED STATES OF AMERICA, ex rel. TARYN HARTNETT and DANA SCHOCHED.

Plaintiff,

v.

PHYSICIANS CHOICE LABORATORY SERVICES, LLC, DOUGLAS SMITH, PHILIP MCHUGH AND MANOJ KUMAR,

Defendants.

DEFENDANT MANOJ KUMAR'S

ANSWER TO THE

UNITED STATES COMPLAINT
IN INTERVENTION

Defendant Manoj Kumar, by and through undersigned counsel, hereby answers and responds to the United States Complaint in Intervention as follows:

UNITED STATES COMPLAINT IN INTERVENTION

The introductory paragraph characterizes the intention and purpose of the United States in bringing this action and makes broad, general and conclusory allegations against individuals and entities other than this defendant and therefore requires no answer or response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

I. NATURE OF ACTION

- 1. This paragraph states legal conclusions and characterizes the purpose of the United States in bringing this action and therefore requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 2. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 3. This paragraph makes no allegations pertaining to this defendant and therefore requires no response by him. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 4. This paragraph makes no allegations pertaining to this defendant and therefore requires no response by him. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 5. This paragraph makes allegations pertaining to other individuals to which no response is required by this defendant. As to those allegations, to the extent an answer or response is required, they are denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph. The allegations pertaining to this defendant are denied.

- 6. This paragraph makes allegations pertaining to other individuals to which no response is required by this defendant. As to those allegations, to the extent an answer or response is required, they are denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph. The allegations pertaining to this defendant are denied.
- 7. This paragraph states legal conclusions to which no response is required. To the extent the paragraph makes factual allegations against this defendant, such allegations are denied.
- 8. This paragraph makes allegations pertaining to an entity and individuals other than this defendant and to that extent, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph. The allegations pertaining to this defendant are denied.

II. JURISDICTION AND VENUE

- 9. This paragraph states legal conclusions to which no response is required. To the extent that a response is required, defendant asserts no defense based on subject matter jurisdiction.
- 10. This paragraph states legal conclusions to which no response is required. To the extent that a response is required, defendant asserts no defense of lack of personal jurisdiction.
- 11. This paragraph states legal conclusions to which no response is required. To the extent that a response is required, defendant asserts no defense of improper venue.

III. PARTIES

12. This paragraph characterizes the nature and purpose of this action and to that extent requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

- 13. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 14. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 15. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 16. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 17. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 18. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 19. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 20. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 21. Admitted that Mr. Kumar was an independent contractor for PCLS and later an employee. Admitted that Mr. Kumar has owned several businesses providing management and billing services to health care providers. Except as admitted, the allegations are denied.
- 22. This paragraph is too vague and broad to permit a specific response. To the extent that an answer or response is required, it is denied for lack of sufficient information to form a belief as the truth of the allegations in this paragraph.

IV. THE LAW

The False Claims Act

- 23. This paragraph quotes an excerpt from the statutes and requires no response by this defendant. To the extent a response is required, defendant relies on and incorporates the full text of the statute.
- 24. This paragraph quotes an excerpt from the statutes and requires no response by this defendant. To the extent a response is required, defendant relies on and incorporates the full text of the statute.
- 25. This paragraph synthesizes and summarizes a statute and requires no response by this defendant. To the extent a response is required, defendant relies on and incorporates the full text of the statute.

The Anti-Kickback Statute

- 26. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- This paragraph states legal conclusions and requires no response by this defendant. This paragraph quotes an excerpt from the statutes and requires no response by this defendant. To the extent a response is required, defendant relies on and incorporates the full text of the statute. To the extent further answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 28. This paragraph states legal conclusions and requires no response by this defendant. This paragraph quotes an excerpt from the statutes and requires no response by this defendant. To the extent a response is required, defendant relies on and incorporates the full text of the statute.

To the extent further answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

- 29. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 30. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 31. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 32. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 33. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 34. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 35. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 36. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 37. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 38. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

39. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

The Medicare Program

- 40. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 41. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 42. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 43. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 44. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 45. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

- 46. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 47. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 48. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 49. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 50. This paragraph quotes an excerpt from the regulations and requires no response by this defendant. To the extent a response is required, defendant relies on and incorporates the full text of the applicable regulations.
- 51. This paragraph states legal conclusions and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 52. This paragraph pertains to another defendant and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - 53. Admitted.
 - 54. Admitted.

Admitted
Admitted

58. Admitted.

57.

Admitted.

59. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

60. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

61. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

62. Denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

Medicare Coverage for Laboratory Tests

63.	Admitted.	
64.	Admitted.	
65.	Admitted.	
66.	Admitted.	
67.	Admitted.	
68.	Admitted.	
69.	Admitted.	
		HHS-OIG Guidance to Clinical Laboratories
70.	Admitted.	
71.	Admitted.	

V. FACTUAL BACKGROUND

A. Urine Drug Testing

72.	Admitted.
73.	Admitted.
74.	Admitted.
75.	Admitted.
76.	Admitted.
77.	Admitted.
78.	Admitted.
79.	Admitted.
80.	Admitted.
81.	Admitted.
82.	Admitted.
83.	Admitted.
84.	Admitted.
85.	Admitted.
86.	Admitted.
87.	Admitted.
88.	Admitted.
89.	Admitted.
90.	It is admitted that quantitative UDTs should be based on the medical judgment and
discretion of i	ndividual physicians.

B. Reimbursement for Urine Drug Tests

- 91. Admitted.
- 92. Admitted.
- 93. Admitted.
- 94. Admitted.
- 95. Admitted.
- 96. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 97. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - 98. Admitted.
 - 99. Admitted.

C. PCLS Business Practices

- 100. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 101. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

- 102. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 103. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 104. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 105. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 106. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - 107. Admitted.
- 108. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 109. This paragraph pertains to other defendants and requires no response by this defendant. To the extent an answer or response is required, it is denied for lack of knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - 110. Denied.

- 111. Admitted.
- 112. Denied.
- 113. Denied.
- 114. Denied for lack of information and belief.
- 115. Denied for lack of information and belief.
- 116. Denied for lack of information and belief.
- 117. Denied for lack of information and belief.
- 118. Denied for lack of information and belief.
- 119. Denied for lack of information and belief.
- 120. Denied for lack of information and belief.
- 121. Denied for lack of information and belief.
- 122. Denied for lack of information and belief.
- 123. Denied for lack of information and belief.
- 124. Denied.
- 125. Denied.
- 126. Denied.

D. Defendant Smith's Kickbacks to Pain Clinic

- 127. Denied for lack of information and belief.
- 128. Denied for lack of information and belief.
- 129. Denied for lack of information and belief.
- 130. Denied for lack of information and belief.
- 131. Denied for lack of information and belief.
- 132. Denied for lack of information and belief.

- 133. Denied for lack of information and belief.
- 134. Denied for lack of information and belief.
- 135. Denied for lack of information and belief.
- 136. Denied for lack of information and belief.
- 137. Denied for lack of information and belief.
- 138. Denied for lack of information and belief.
- 139. Denied for lack of information and belief.
- 140. Denied for lack of information and belief.
- 141. Denied for lack of information and belief.
- 142. Denied for lack of information and belief.
- 143. Denied for lack of information and belief.
- 144. Denied for lack of information and belief.
- 145. Denied for lack of information and belief.
- 146. Denied for lack of information and belief.
- 147. Denied for lack of information and belief.
- 148. Denied for lack of information and belief.
- 149. Denied for lack of information and belief.
- 150. Denied for lack of information and belief.
- 151. Denied for lack of information and belief.
- 152. Denied for lack of information and belief.
- 153. Denied for lack of information and belief.
- 154. Denied for lack of information and belief.
- 155. Denied for lack of information and belief.

156.	Denied for lack of information and belief.
157.	Denied for lack of information and belief.
158.	Denied for lack of information and belief.
	E. Defendants McHugh and Kumar Provide Analyzers to Physicians
159.	Denied.
160.	Denied.
161.	Admitted.
162.	Admitted.
163.	Denied for lack of information and belief.
164.	Admitted.
165.	Admitted.
166.	Admitted.
167.	Admitted.
168.	Admitted.
169.	Admitted.
170.	Denied.
171.	Denied.
172.	Admitted.
173.	Denied.
174.	Denied.
175.	Denied.
176.	Denied.
	1. McHugh and Kumar Provide Analyzer to John Johnson in Exchange for

Referrals.

- 177. Admitted.
- 178. Denied for lack of information and belief.
- 179. Denied for lack of information and belief.
- 180. Denied for lack of information and belief.
- 181. Denied for lack of information and belief.
- 182. Denied for lack of information and belief.
- 183. Denied for lack of information and belief.
- 184. Denied for lack of information and belief.
- 185. Denied for lack of information and belief.
- 186. Admitted.
- 187. Denied for lack of information and belief.
- 188. Denied for lack of information and belief.
- 189. Admitted.
- 190. Admitted.
- 191. Denied.
- 192. Denied.
- 193. Admitted.
- 194. Admitted.
- 195. Denied for lack of information and belief.
- 196. Denied.
- 197. Admitted.
- 198. Denied for lack of information and belief.

- 199. Denied for lack of information and belief.
- 200. Denied for lack of information and belief.
- 201. Denied for lack of information and belief.
- 202. Denied for lack of information and belief.
- 203. Denied for lack of information and belief.
 - 2. McHugh and Kumar Provide Analyzer to Dr. John Nickels
- 204. Denied for lack of information and belief.
- 205. Denied.
- 206. Denied.
- 207. Denied for lack of information and belief.
- 208. Admitted.
- 209. Denied.
- 210. Denied.
- 211. Denied for lack of information and belief.
- 212. Admitted.
- 213. Admitted.
- 214. Denied for lack of information and belief.
- 215. Admitted.
- 216. Denied for lack of information and belief.
- 217. Admitted.
- 218. Denied for lack of information and belief.
- 219. Denied for lack of information and belief.

F. Kumar Receives Remuneration for Providing Samples from Physicians

220.	Denied as to characterization of "inducement schemes", otherwise admitted.
221.	Admitted.
222.	Denied.
223.	Denied.
224.	Admitted.
225.	Admitted.
226.	Denied for lack of information and belief.
227.	Admitted.
228.	Denied for lack of information and belief.
229.	Denied.
230.	Denied for lack of information and belief.
231.	Denied for lack of information and belief.
232.	Denied.
232.	Denied. G. McHugh lends \$2 million to Pain Management Doctor
232.233.	
	G. McHugh lends \$2 million to Pain Management Doctor
233.	G. McHugh lends \$2 million to Pain Management Doctor Admitted.
233.234.	G. McHugh lends \$2 million to Pain Management Doctor Admitted. Denied for lack of information and belief.
233.234.235.	G. McHugh lends \$2 million to Pain Management Doctor Admitted. Denied for lack of information and belief. Denied.
233.234.235.236.	G. McHugh lends \$2 million to Pain Management Doctor Admitted. Denied for lack of information and belief. Denied. Denied for lack of information and belief.
233.234.235.236.237.	G. McHugh lends \$2 million to Pain Management Doctor Admitted. Denied for lack of information and belief. Denied. Denied for lack of information and belief. Admitted.
233.234.235.236.237.238.	G. McHugh lends \$2 million to Pain Management Doctor Admitted. Denied for lack of information and belief. Denied. Denied for lack of information and belief. Admitted. Denied for lack of information and belief.
233.234.235.236.237.238.239.	G. McHugh lends \$2 million to Pain Management Doctor Admitted. Denied for lack of information and belief. Denied. Denied for lack of information and belief. Admitted. Denied for lack of information and belief. Admitted. Admitted.

- 242. Denied for lack of information and belief.
- 243. Denied for lack of information and belief.
- 244. Denied for lack of information and belief.

H. McHugh and Kumar Lend \$50,000 to Physician

- 245. Admitted.
- 246. Admitted.
- 247. Denied.
- 248. Admitted.
- 249. Admitted.
- 250. Admitted.
- 251. Admitted.
- 252. Admitted.
- 253. Admitted.
- 254. Denied for lack of information and belief.

(False Claims Act: Presentation of False Claims) (31 U.S.C. §3729(a)(1)(A))

- 255. Defendant incorporates all answers and responses previously made.
- 256. Denied for lack of information and belief.
- 257. Denied.
- 258. Denied.
- 259. Denied.
- 260. Denied.

COUNT II

(False Claims Act: Presentation of False Statements Material to False Claims) (31 U.S.C. §3729(a)(1)(B))

- 261. Defendant incorporates all answers and responses previously made.
- 262. Denied.
- 263. Denied.
- 264. Denied.

COUNT III (Payment by Mistake of Fact)

- 265. Defendant incorporates all answers and responses previously made.
- 266. Denied.
- 267. Denied.
- 268. Denied.

COUNT IV (Unjust Enrichment)

- 269. Defendant incorporates all answers and responses previously made.
- 270. Denied.
- 271. Denied.

STATUTE OF LIMITATIONS DEFENSE

- 272. The claims against this defendant are controlled by the statute of limitations established by 31 U.S.C. §3731(b).
- 273. The United States was on notice of the facts material to the claims made in this action no later than November 2014, when the related qui tam action was initially filed.

- 274. The United States had until November 2017 to bring action against defendant unless any such claims were saved by the statutory provision allowing it to go back six years to seek recovery for violations of the False Claims Act.
- 275. The United States took no action to toll the running of the statute of limitations against this defendant until after November 2017.
 - 276. The United States did not commence this action against defendant until June 2019.
- 277. The United States seeks recovery from this defendant for acts that occurred more than six years prior to June 2019.
- 278. The United States seeks recovery from this defendant for acts that occurred more than six years prior to any tolling agreement.
- 279. All claims that arose more than six years from June 2019 or any tolling agreement regarding the statute of limitations are barred by the statute of limitations.

PRAYER FOR RELIEF

WHEREFORE, Defendant Manoj Kumar, respectfully requests the following relief:

- 1. This action be dismissed with prejudice;
- 2. This Court enter an Order barring the United States from seeking relief for actions occurring more than six years prior to June 2019;
 - 3. That the United States have and recover nothing from this defendant;
 - 4. That judgment be entered in favor of Defendant Kumar;
 - 5. That the Court allow a trial by jury on all issues so triable;

All such other and further relief that the Court finds just and proper
 This the 23rd day of September, 2019.

s/ C. Melissa Owen

C. Melissa Owen
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s/ William Simpson

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COUNSEL FOR MR. MANOJ KUMAR

CERTIFICATE OF SERVICE

I certify that I have this day served a copy of the above upon the attorneys for the United States of America, that is, Jonathan Ferry, by ECF at jonathan.ferry@usdoj.gov.

This the 23rd day of September, 2019.

s/ C. Melissa Owen

C. Melissa Owen TIN FULTON WALKER & OWEN, PLLC North Carolina Bar # 28903 301 East Park Avenue Charlotte, NC 28203 Phone: 704-338-1220

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COUNSEL FOR MR. MANOJ KUMAR